

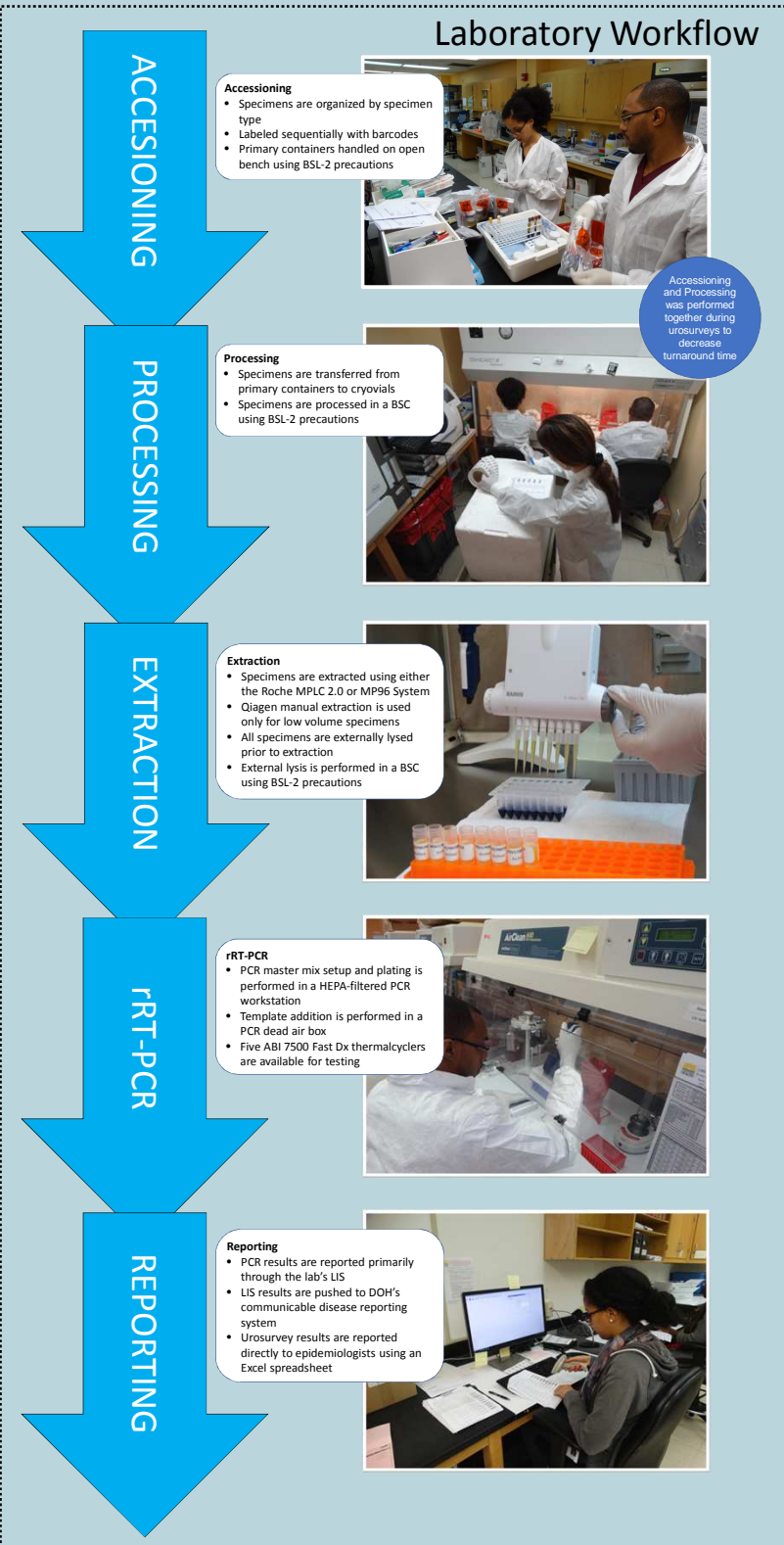
Rapid Implementation of Zika RT-PCR Testing in Anticipation of an Outbreak Response: Lessons Learned at the Bureau of Public Health Laboratories-Miami



Stephen L. White, Darryl Pronty, Anggy Sebastiani, Noemi Vega, Elesi Quaye, and Leah D. Gillis
Florida Bureau of Public Health Laboratories-Miami, Miami, FL

Abstract

During the first seven months of 2016, the Florida Department of Health (FDOH) identified 321 travel-related cases of Zika virus infections amongst residents and visitors to Florida (Likos et al., 2016). Of the three laboratories of the FDOH's Bureau of Public Health Laboratories, only two locations (Jacksonville and Tampa) were supporting these investigations by testing specimens for Zika virus. In early July 2016, epidemiological and laboratory evidence began to mount toward autochthonous transmission of the virus in a limited area in Miami-Dade County, Florida. In response, BPHL-Miami began preparations to perform high-throughput testing of specimens to support an outbreak response. By the end of July BPHL-Miami had implemented the Centers for Disease Control and Prevention's Trioplex Real-time RT-PCR Assay and was prepared to test the high volume of specimens associated with the forthcoming outbreak and provide timely, sustained support for the ensuing epidemiological investigations. From July to December 2016, BPHL-Miami tested approximately 6,000 specimens by real-time PCR. During this period, several workflow changes were made to adapt the testing process to the optimum configuration for the high volume of specimens the laboratory was experiencing. Herein, we report the lessons learned as a result of this experience and offer a model for high-throughput laboratory testing.



Regulatory Issues

Several factors played a role in considering the adoption of the CDC's Trioplex Assay over other available PCR tests.

- FDA approval of the assay through the Emergency Use Authorization (EUA) provided increased value
- The availability of a verification panel of specimens allowed for the rapid implementation of the assay
- Strict adherence to the EUA limited specimen choice and required a public health surveillance exemption for epidemiological investigations using urine alone



Each specimen was archived in pre-labeled 1.2mL cryovials. This allowed for:

- Long-term storage of specimens for retesting or special projects
- Easier manipulation of specimens
- Reduced storage needs for specimens
- Readiness for an unexpected surge in specimens

An adjustable-spacer multichannel pipette can be used to expedite several key tasks:

- Transferring specimens from cryovials to extraction plates
- Transferring nucleic acid extracts from output plate to archive tubes

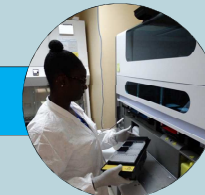


Roche MagNA Pure LC 2.0

- 32 specimens in approximately 2 hours

Roche MagNA Pure 96 System

- 96 specimens in approximately 1 hour
- Effectively sextuples extraction capacity compared to MPLC 2.0

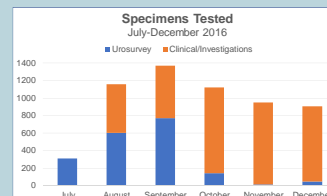
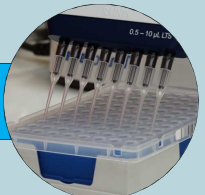


Using a multichannel pipette to add master mix to the 96-well reaction plate offers several advantages:

- Rapid plating
- Fewer mistakes
- Easier to plate multiple plates

Using a multichannel pipette for template addition offers several benefits:

- Faster than a single channel pipette
- Less prone to skipping wells



Staffing

Adequate staffing is critical to continue such surge testing long-term. When this testing was brought online, only two laboratorians were able to perform the assay. Additional staff members were hired during the ensuing months leading to additional issues.

- How are new laboratorians trained?
- How is this done quickly while maintaining the increased testing level?

Discussion

Flexibility is critical when approaching a surge situation in the laboratory. Many changes were made to our normal workflow in order to successfully handle a substantial increase in the test volume for Zika virus. Some of these adaptations were made prior to this increase whereas some were implemented as the need arose.

The tips presented here are generally applicable to many situations where molecular testing demands are increased. For example, we believe our experiences with this Zika virus outbreak can be easily applied to surge testing for pandemic influenza or other infectious diseases. Further, many of these adaptations can be used on a daily basis to increase efficiency in the laboratory in general.